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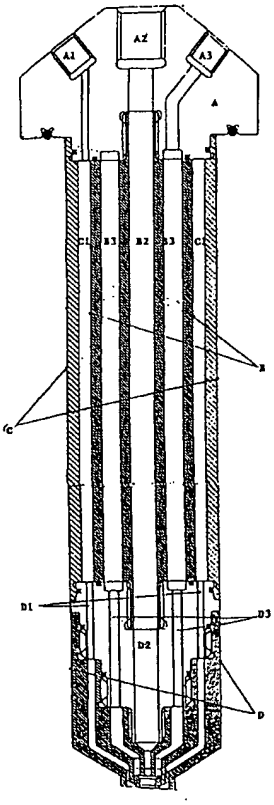
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SPRAY UNIT OF A SPRAY DRYER



(57) Abstract: A spray unit for spray dryer to be used for microincapsulation of solid particles during which the contact between particles and solvent occurs only in the final phase of the spray process making the dissolution or the solvent action practically irrelevant.

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"Spray unit of a spray dryer"

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The present invention relates to a spray unit for spray dryer useful for the microincapsulation of solid particles.

The microincapsulation by spray dryer normally used a suspension of particles to coat in the solution or in the coating suspension.

This method has a limited application when the particles to be coated are soluble in the coating mixture or, for chemical incompatibility, they cannot be in touch with the coating liquid for a long time (for example proteins or substances subjected to the solvents action, etc).

Furthermore, the environmental pollution problems and danger in the use of organic solvents, always carried out the use of coating agents expressed on water base and this makes practically impossible the use of spray dryer in the microincapsulation of water-soluble particles with the conventional method.

Object of the present invention is a particular model of spray unit which allow to solve the above mentioned problems and allow to use spray dryer equipment's also for applications which need a reduced contact time of the solution or coating suspension with the particles to be coated.

In fact, the contact between the particles and the coating agent is carried out only in the final phase of the spray process being the dissolution or the action of the liquid element to vaporize from the coating agent practically irrelevant.

The spray unit of the present invention can be used as well as the case of conventional microincapsulation that is when the particle to be coated is insoluble in the coating medium, also in the case of particles soluble in the coating medium and also in the case that substances subjected to the solvent action are to be microincapsulated (for example peptides, proteins and degradable substances due to the same solvent).

The use of the spray unit according to the present invention allows the application of the spray dryer method to coat particles of diameter 10-500 μm soluble in the coated liquid.

A second application is to coat the particles of the above mentioned diameter and insoluble in the coated liquid.

A further application is to coat the particles of the above mentioned diameter subjected to the solvents action contained in the coated liquid.

By using a spray dryer equipped with a spray unit according to the present invention, microcapsules gastroresistant can be obtained, prolonged release, delayed release and taste-making microcapsules.

The coating liquid is the solution or the suspension of the substance which will coat the particles in the selected solvent or solvents, water included.

The useful coating to obtain these capsule can be methacrylic acid polymeric derivatives, cellulose derivatives, lipids and their mixtures.

The spray unit of the invention is manufactured in stainless steel (or other material compatible with the products used) and it is duly drilled and shaped in order to allow the transit of particles, of the coating suspension or solution and of the air, by assuring at the same time the best isolation from the external environment and among the pipes.

It can be applied on different types of spray dryer equipment with minimum changes obvious for the man skilled in the art, such as the choice the threading fit suitable for the screw on the equipment, the length and the diameter according to the specific characteristics of the equipment used.

The drawings and the description of the technical points of view reported here below refer in particular to a spray unit suitable for a spray dryer BUCHI B191.

The diameter of the spray unit parts can be modified according to the specific microincapsulation process to be carried out with the spray dryer.

The following drawings and their description refer in particular to the microincapsulation for obtaining gastroresistant pharmaceutical forms.

However, it is obvious that the spray unit according to the present invention can be used without substantial changes of other kind of applications not belonging to the pharmaceutical field such as coated granules for food, dietetic, cosmetic and phytosanitary use.

The spray unit object of the invention consists in four fundamental parts, described here below, as stated in figure 1: top part (A), core (B), jacket (C), bottom part (D).

Top part (A)

It is the spray unit side where the air is introduced and where the particles and the coating solution or suspension are charged.

It is equipped with 3 pipes built up to insert special connectors stated with A1=air, A2=particles and A3= coating solution or suspension.

The filling of the powders is performed by a mechanic or pneumatic system that allows the particles to pass though the pipe.

The cylindrical shape shown in table 1 with its frustum of cone end can be modified according to the insertions and adjustments necessary to join it to the specific spray dryer on which it is placed.

Core (B)

The core is the central and more internal side of the nozzle working as support and connection between the top part and the bottom one.

The core has a cylindrical shape and it is equipped with a central pipe (B2) for the transfer of particles and with two side pipes (B3) for the transfer of the coating solution or suspension. Either B2 pipe or B3 lead directly into the overlooking side lodged in the top part that is A2 and A3 respectively.

Jacket (C)

The jacket consists of a connection pipe between the bottom part (D) and the top one (A) and it is placed in a concentric position with respect to the core.

The space between jacket and core works as transit tube for the air (C1). The seal is guaranteed by suitable rubber rings (O-rings).

Bottom part (D)

The bottom part is the spray unit side working as support for the different groups of nozzles. It consists of a central pipe (D2) for the transit of the powders directly in communication with the overlooking pipe (B2), of different pipes for the transit of coating solution or suspension (D3) and of different pipes for the air transit (D1).

These last two kinds of pipes (the one for the coating liquid and the one for the air) are placed round in a circle with respect to the central pipe and their number ranges from 1 to 250 with respect to the spray unit size and of the quantity of liquid to transfer.

Furthermore, the bottom part D of the spray unit is shown in figure 2.

It consists of three particular caps L, M and N which introduced in the bottom part (figure 2) convey the particles coming from pipe D2, the coating liquid coming from pipe D3 and the air coming from pipe D1 in a sole point (E).

All these pipes connect directly with the overlooking pipes C2, C3 and C1 respectively.

The length of the caps in the exit point can be modified by a mechanic screw system, for example, according to the type of process and of the instrumental operating parameters. For example the position of the nozzle of cap N can be moved up to and over the limits of the nozzle of the cap L which is showed as point K in figure 2.

The diameters of the pipes for the transfer of particles, liquids and air range between 1 e 500 mm according to the kind of manufacturing to carry out.

The diameters of the nozzles range between 1 and 400 mm according to the manufacturing to carry out.

The spray unit according to the present invention can be modified to adjust it to spray dryers different from BUCHI B191 as referred in the figures.

For example, the man skilled in the art can modify the shape of the top part (A) to adjust it to others spray dryers, can increase the number of pipes B3 and make them as a whole concentric on B2.

The length of the whole spray unit can change according to the kind of spray dryer on which it is applied.

The length of the pipes and the diameter of the jacket which are not critical in themselves as far as the microincapsulation process is concerned too, can change according to the type of spray dryer on which the nozzle is applied.

Obviously, these changes do not move from the object of the present invention that is allowing the use of spray dryers also in conditions that were not possible before.

We report herewith, as example, the description of the practical application of the spray unit object of the invention.

The solid particles enter on the spray unit from the connector A2, passing through pipe B2 and D2 up to the mixing area E.

The coating liquid arrives from the connector A3, goes through pipe B3 and D3 up to the mixing area E.

The air is introduced from the connector A1, goes through the pipes C1 and D1 up to the mixing area E.

The solid particles, the liquid and the air meet in E from which the spray in the hot air streams starts.

Claims

1. Spray unit which allows the particles to be coated by spray dryer also in conditions that require a reduced contact time between the coating solution or suspension and the particles to be coated, according to what is described and reported in figures 1 and 2.
2. Spray unit according to claim 1 to coat particles water-soluble.
3. Spray unit according to claim 1 to coat particles insoluble in the coated liquid.
4. Spray unit according to claim 1 to coat particles subjected to the action solvents contained in the coating liquid.
5. Spray unit according to claims 2, 3, or 4 to coat of 10-500 μm diameter particles.
6. Spray unit having four fundamental parts: top part (A), equipped with 3 pipes, where the air is introduced and where the particles and the coating solution or suspension are charged; core (B) cylindrically shaped equipped with a central pipe (B2) for the transfer of particles and with two side pipes (B3) for the transfer of the coating solution or suspension, acting as support and connection between the top part (A) and the bottom one (D), jacket (C) placed in a concentric position with respect to the core (B) so as the space between the jacket (C) and the core (B) acts as a transit tube for air connecting the top part (A) and the bottom part (D); bottom part (D) spray unit side consisting of a central pipe (D2) for the transit of the powders directly in communication with the overlooking pipe (B2), of different pipes for the transit of coating solution or suspension (D3) and of different pipes for the air transit (D1) and acting as support for the different groups of nozzles.
7. A spray unit according to claim 6 wherein in the bottom part (D), the transit pipes (D3) and (D1) are in a number from 1 to 250.

FIG 1

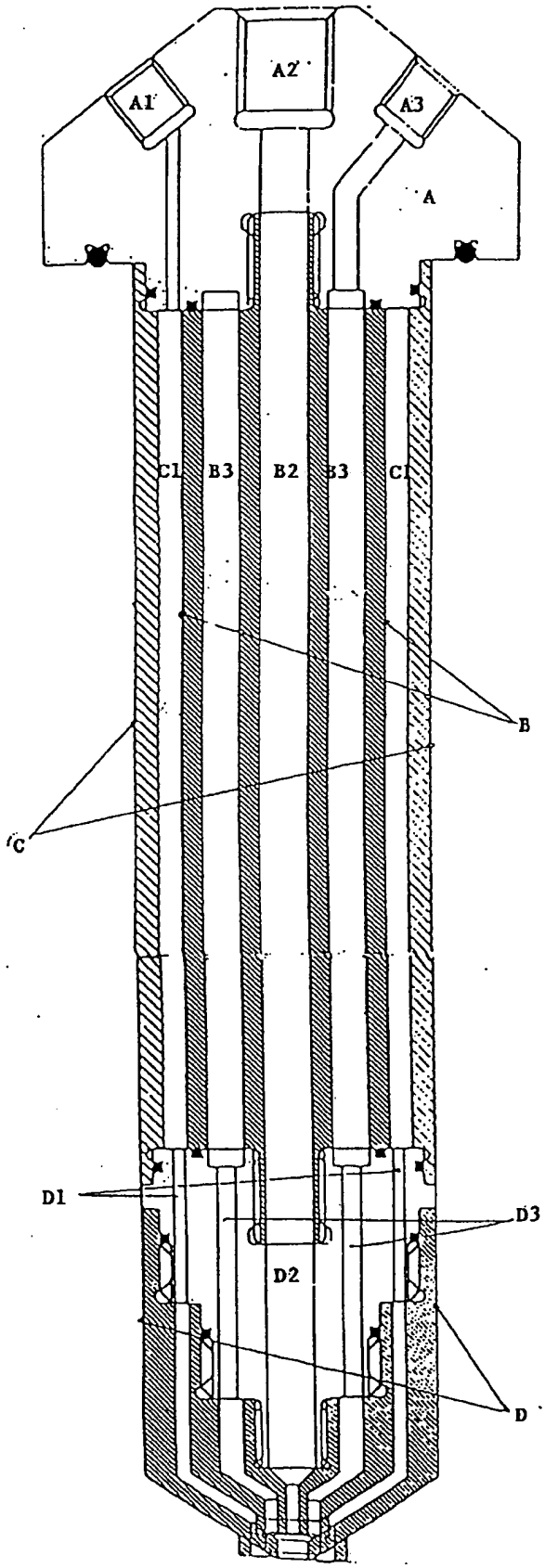
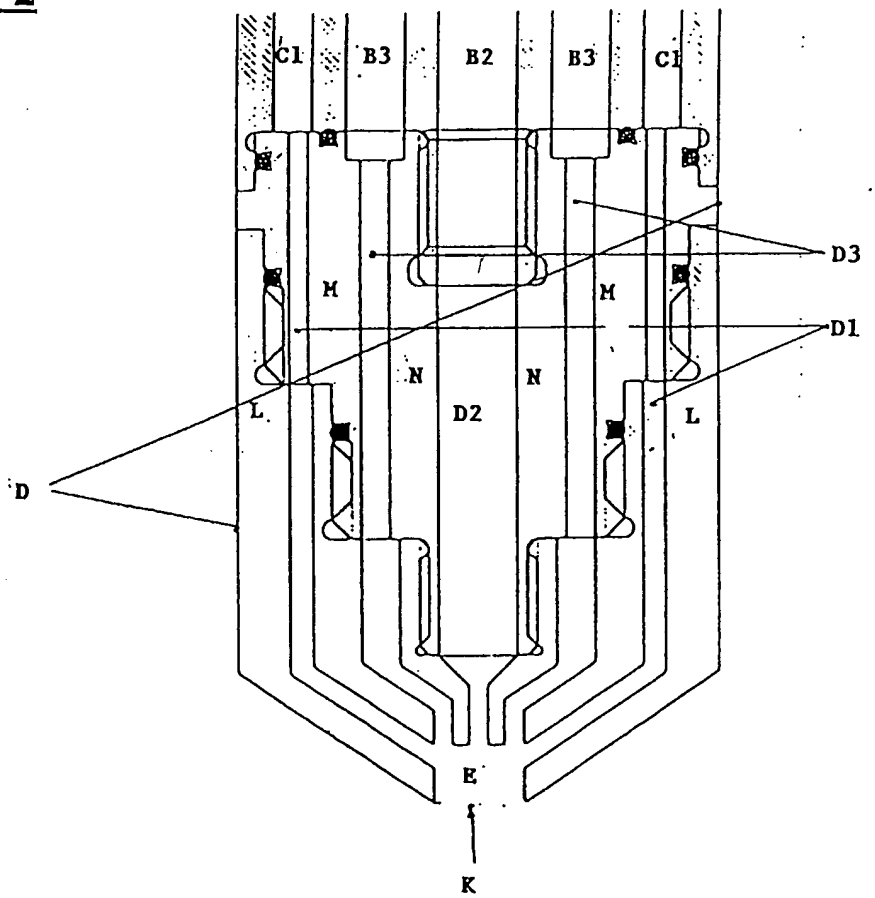


FIG 2



INTERNATIONAL SEARCH REPORT

International Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 B01J13/04 B01D1/18 B01D1/20 B05B7/14 B01J2/00
F26B3/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 B01J B01D B05B F26B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 27 46 489 A (JUNGINGER HANS DR) 19 April 1979 (1979-04-19) page 8; figure 1	6,7
X	US 5 032 222 A (MILLIOUD ALAIN) 16 July 1991 (1991-07-16) abstract column 5, line 40 - line 66; figure 5	6,7
X	US 3 770 207 A (MULLER F ET AL) 6 November 1973 (1973-11-06) abstract column 1, line 59 -column 2, line 20; figure 1	6,7

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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Date of the actual completion of the international search	Date of mailing of the international search report
7 March 2003	18/03/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3018	Thomasson, P

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 02/14465

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	DE 199 27 537 A (MERCK PATENT GMBH) 21 December 2000 (2000-12-21) column 3, line 53 -column 4, line 9; figure 2	6,7
X	US 4 033 512 A (BECK LOUIS) 5 July 1977 (1977-07-05) column 1, line 5 - line 33 column 3, line 40 - line 57; figure 5	6,7
X	US 3 949 096 A (JOHNSON LAWRENCE A ET AL) 6 April 1976 (1976-04-06) column 1, line 12 - line 68; figure 1 column 4, line 54 -column 5, line 24	6,7
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X	DE 43 29 205 A (DEGUSSA) 2 March 1995 (1995-03-02) abstract; figure 1 page 3, line 24 - line 35	6,7

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1-5

Claim 1 solely indicates a spray unit "according to what is described and reported in figures 1 and 2"; claim 1 does not indicate any concrete technical feature in order to characterize the claimed spray unit. Furthermore the statement "...which allows the particles to be coated by spray dryer also in conditions that require a reduced contact time..." corresponds to "a result to be achieved". The corresponding technical features are not indicated in claim 1. Therefore claim 1 and the dependent claims 2-5 fail to comply with the clarity requirement of Article 6 PCT to such an extent that a meaningful search is impossible. Consequently the search has been carried out for those parts of the application which do appear to be clear, namely claims 6 and 7.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP 02/14465

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 1-5
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP 02/14465

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